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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,712	04/21/2009	Sergey I. Chernysh	SPSUP0101WOUS	4343
23908 7590 08/18/2011 RENNER OTTO BOISSELLE & SKLAR, LLP 1621 EUCLID AVENUE NINETEENTH FLOOR CLEVELAND, OH 44115			EXAMINER FIEBIG, RUSSELL G	
			ART UNIT 1655	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,712	Applicant(s) CHERNYSH, SERGEY I.
	Examiner RUSS FIEBIG	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1006</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|---|--|

DETAILED ACTION

Applicant's election with traverse of *Libellula quadrimaculata* (Claims 1-4, 7 and 8 were elected) in the reply filed on July 20, 2011 is acknowledged. The applicant's traversal is on the grounds that the individual species listed in the original claims do not present a serious burden on the Examiner. However, there is often a large degree of intraspecies diversity within particular species, as well as differences within genera, families and orders. Given the enormous number of insect species that would have to be searched this would pose a substantial burden. Applicant indicates that because the international search authority did not specifically object to the large number of species claimed that this is evidence that the search would not be a serious burden. However, the search performed by the ISA is a preliminary search and not an examination on the merits.

Therefore, the requirement is still deemed proper and is made FINAL.

Claims 1-4, 7 and 8 are presented for examination on the merits (claims 5, 6 and 9-41 are withdrawn as being drawn to a non-elected invention).

Objections

Pterygota is the correct spelling of the subclass of winged insects, deriving from the Greek root ptery for "feather, wing, winglike". The word is repeatedly misspelled throughout the application.

The word "of" is apparently missing between "cuticle" and "the" in line 2 of claim 2.

Chromatography is misspelled in claim 3.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some particular examples of insects, including the elected species, does not reasonably provide enablement for any and all insects of the subclass *Pterygota*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

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With respect to the *Wands* factors above (particularly as they pertain to the quantity of experimentation necessary as well as the state of the prior art within the field and the amount of direction or guidance presented), applicant has reasonably demonstrated/disclosed that they have extracted antiviral proteins from a number of genera/order/species. However, the size of the subclass *Pterygota* is enormous so it would require undue experimentation to practice the full scope of the instantly claimed invention given the relative skill of those skilled in the art and the amount of guidance provided by the instant specification. The subclass *Pterygota* includes practically all common insects and is the main branch of the class *Hexapoda*. Appropriate given the name *Pterygota*, this subclass includes all insects that have or had at one time wings. While the instant specification describes a large number of examples of genera, orders and/or species within this subclass, this represents a relatively small number given the enormous size of the subclass.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of art the art make and/or use the instantly claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 and 3 recites the limitation "supernatant" in line 4 and 2, respectively. There is insufficient antecedent basis for this limitation in the claim. It is unclear what supernatant applicant means, presumably this supernatant is produced by the centrifugation step. But as currently drafted, this is not clear. Appropriate correction is requested.

Claim 1 is rendered vague and indefinite by the term "column." It is unclear whether this refers to a chromatography column, since applicant has not clearly stated that the chromatography is actually column chromatography. Appropriate clarification is requested.

Claim 2 recites the limitation "the cuticle" in line 2. There is insufficient antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph, for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by Chernysh et al. (2002) and Kim et al. (US6337093).

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An antiviral substance comprising hemolymph of insects of subclass Pterygota is instantly claimed.

Chernysh et al. teach antiviral and antitumor peptides from insects, specifically the blow fly *Calliphora vicina* (Diptera) within subclass Pterygota. Furthermore, the method by which the antiviral substance(s) are obtained is disclosed. Diapausing larvae were experimentally infected by pricking the cuticle with a fine needle dipped into a mixture of heat-killed bacteria (e.g., *E. coli*, *Micrococcus luteus*) followed by hemolymph collection, centrifugation and purification of the supernatant by chromatography (see entire document, including e.g., pg. 12628-12629).

Kim et al. teach a pharmaceutical composition for which insects are used as the source for production of the composition, that is peptides (oligo- and poly-), proteins or a mixture of peptides made from the hemolymph of the insects *Calliphora* of the order Diptera (i.e., within subclass Pterygota), a method for production and use thereof for treating viral infections. Furthermore, it is known that active agents can be isolated from body fluids (e.g. hemolymph) or synthesized. Kim et al. further teach that the antiviral composition is obtained by first vaccinating an invertebrate with bacteria followed sequentially by the steps of collecting, centrifuging and chromatographically separating the body fluid to obtain a fraction with activity. (see entire document including, e.g., column 2, lines 14-38; claim 1).

Consequently, the claimed substance is deemed to be anticipated by each of the cited references.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as obvious over Chernysh et al. (2002), in view of Kim et al. (US6337093).

An antiviral substance comprising hemolymph of insects of subclass Pterygota is instantly claimed.

Chernysh et al. beneficially disclose antiviral and antitumor peptides from insects, specifically the blow fly *Calliphora vicina* (Diptera). Furthermore, the method by which the antiviral substance(s) are obtained is disclosed. Diapausing larvae were experimentally infected by pricking the cuticle with a fine needle dipped into a mixture of heat-killed bacteria (e.g., *E. coli*, *Micrococcus luteus*) followed by hemolymph collection, centrifugation and purification of the supernatant by chromatography (see entire document, including e.g., pg. 12628-12629). Chernysh et al. does not specifically disclose the use of insects other than *Calliphora vicina* for preparation of the antiviral peptides.

Kim et al. beneficially disclose a pharmaceutical composition for which insects are used as the source for production of the composition, that is peptides (oligo- and poly-), proteins or a mixture of peptides made from the hemolymph of the insects *Calliphora* of the order *Diptera*, a method for production and use thereof for treating viral infections. Furthermore, it is known that

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active agents can be isolated from body fluids (e.g. hemolymph) or synthesized. Kim et al. further teach that the antiviral composition is obtained by first vaccinating an invertebrate with bacteria followed sequentially by the steps of collecting, centrifuging and chromatographically separating the body fluid to obtain a fraction with activity. It is further disclosed that the body fluid may be obtained from insects from a variety of orders/family/genera. (see entire document including, e.g., column 2, lines 14-38; claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide antiviral compositions of the hemolymph of insects from the subclass *Pterygota*, order *Odonata*, family *Libellulidae*, for the following reasons. While the cited references do not explicitly disclose that dragonflies of *Libellula* genus may be used in the disclosed methods of extracting antiviral substances from the insects, the use of other insects from various genera/families/orders is known from Kim et al. Therefore, a person within the field working on the problem of producing antiviral proteins from insects would be motivated to use insects of different orders, genera and families within *Pterygota* subclass as a source of the hemolymph and utilize common methodology as taught by Chernysh et al. and Kim et al. to extract an antiviral substance therefrom.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention of an antiviral substance from the hemolymph of insects of dragonflies of *Libellula* genus. Therefore, the invention as a whole was *prima facie* obvious to one of skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSS FIEBIG whose telephone number is (571)270-5366. The examiner can normally be reached on M-Th 8-5, F 8-4 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571)272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rgf

/Christopher R Tate/
Primary Examiner, Art Unit 1655